Guidance on Satisfying
EPA Quality System Requirements for REMAP

NOVEMBER 2000

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ACRONYMS AND ABBREVIATIONS

ANSI	American National Standards Institute
ASQ	American Society for Quality [formerly American Society for Quality Control (ASQC)]
CFR	Code of Federal Regulations
NCER	National Center for Environmental Research
QA	quality assurance
QAS	quality assurance statement
QC	quality control
QMPP	quality management project plan
SOP	standard operating procedure

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INTRODUCTION:

The EPA Quality System has been in place since 1979. The EPA Quality System operates under the authority of Order 5360.1 CHG 1, *Policy and Program Requirements for the Mandatory EPA Quality System* (July 1998). The quality system is employed for work done by EPA employees as well as by contractors and grant recipients. The quality system provides the management and technical practices needed to ensure that environmental data are of adequate quality and usable for their intended purposes. This document has been modified by the ORD Work Group for REMAP. The original document was prepared by USEPA's Quality Assurance staff for the STAR grants program. This guidance should be considered iterative, and should be used as a general guide to develop a quality assurance program plan (QAPP).

1 ENVIRONMENTAL PROTECTION AGENCY QUALITY ASSURANCE REQUIREMENTS

1.1 QUALITY ASSURANCE AND QUALITY SYSTEM REQUIREMENTS

Basic quality terms used in this guidance are defined as follows:

> *Quality assurance (QA)* is an integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality involvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer [American Society for Quality (ASQ), 1994].
>
> *Quality control (QC)* is the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; the operational techniques and activities used to fulfill quality requirements.

The EPA believes strongly in the application of QA principles to all types of environmental studies. In exploratory research studies, products may range from a clear-cut identification of a fundamental photochemical reaction mechanism (which may lead to a better understanding of ozone formation) to a realistic assessment of the efficiency and longevity of a novel catalytic converter for reducing automobile tailpipe emissions. To ensure that such products

are of sufficient and adequate quality for their intended use, the application of QA and QC is both prudent and necessary regardless of the level of complexity of the work undertaken. Accordingly, EPA has established quality system requirements that must be followed within EPA and by extramural contractors and financial assistance recipients for all work performed that involves environmental data production and use.

EPA assistance agreement recipients must implement or have implemented a quality system that conforms to the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ASQ, 1994). This requirement is defined in 40 *Code of Federal Regulations (CFR)* Part 30, *Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations*, as applied to the STAR program (Parts 30.45 and 30.54). Any awards made to State, Tribal, or local governments would be covered by quality requirements defined in 40 CFR Part 31, *Uniform Administrative Requirements for Grants and Cooperative Agreement to State, Tribal, and Local Governments.*

The quality system is to be applied to all environmental programs within the scope of the assistance agreement in accordance with the principle of *graded approach*; that is, the level of detail needed to document quality practices for proposed work depends on the type of work and the intended use of the results. The simpler the project, the less detail will be needed to adequately document the quality practices for the project. However, the intended use of the results will also dictate the extensiveness of the QA and QC documentation needed to substantiate the work performed. The *graded approach* reflects the importance of the work, not just its complexity.

The scope of environmental programs includes direct measurements or data generation; environmental modeling; compilation of data from literature or electronic media; and data supporting the design, construction, and operation of environmental technology. This policy is consistent with all environmental programs operating under the EPA quality system as defined by EPA Order 5360.1, A2, May 2000 (USEPA, 2000)

1.2 BENEFITS OF QUALITY ASSURANCE TO GRANT APPLICANTS

University researchers are generally familiar with the peer review process as it applies to selection of research grants and to the publication of journal articles. EPA believes that as a potential grant applicant considers the approaches that will be taken to achieve the desired results of the research project, the applicant should also identify and document the activities that will ensure that the product is of adequate quality to be used as planned. Such documentation can be very beneficial when a grant application is peer reviewed or a manuscript is submitted for publication. Being able to document that the data in a report or publication meet applicable and appropriate

quality standards or criteria is a positive element in the eyes of many reviewers. A well-designed Quality Management project Plan (QMPP), for example, may also help detect problems or incorrect assumptions before work begins and, thus, avoid false starts or generation of questionable or unusable data sets. Results of a well-conceived experiment can be invalidated by such simple things as misunderstanding verbal directions that could have been written as standard operating procedures (SOPs). (In this context, SOPs are defined as a written document that details the method for performing an operation, analysis, or action with thoroughly prescribed techniques and steps; that is officially approved as the method for performing certain routine or repetitive tasks.) Similarly, an uncalibrated (or improperly calibrated) sensor, such as a pH electrode, can result in many months' worth of data gathered at great expense of time and money being unusable by the researchers. The cost to repeat the experiment may be prohibitive.

Introducing student researchers to QA and QC practices can be part of the total education they will need to compete in today's job market. Quality is a leading force in enabling businesses to compete effectively in international markets. People entering the business world are being expected increasingly to understand basic QA and QC principles and practices and to be proficient in their use. Quality requirements are often viewed as being unnecessary burdens to the conduct of the experiment when, in reality, QA and QC provide prudent safeguards against the occurrence of problems and the introduction of error into the data produced which could have dramatic adverse impacts on the results and the conclusions made from them.

Many exploratory research projects are so novel and uncharacterized that the chances of failure and the uncertainty associated with the data sets are higher than for routine measurement tasks. However, establishing a quality system in the beginning will be an asset and should help lead to future successes. Such a quality system would provide a framework for the early detection of errors and for the documentation of the steps in the experiment to help to assure the reproducibility of the research.

1.3 REQUIRED DOCUMENTATION FOR QUALITY ASSURANCE

Any project involving data collection or processing, conducting surveys, environmental measurements, and/or modeling, or the development of environmental technology (whether hardware-based or via new techniques) for pollution control and waste treatment, must be supported by sufficient and adequate QA and QC practices to assure that the results will be of the type and quality needed and expected for their intended use.

- quality assurance statement and/or
- quality management project plan.

For more details check out the web site at:

http://www.epa.gov/quality

These documents are in pdf format and may be retrieved using ADOBE Acrobat Reader and printed.

2 QUALITY ASSURANCE STATEMENT

2.1 WHAT IS A QUALITY ASSURANCE STATEMENT?

The Quality Assurance Statement (QAS) is a brief description of the quality assurance and quality control practices that will be applied during a research project to assure that the results obtained satisfy the project objectives. Typically, the QAS is presented as a narrative; there is no prescribed format required.

Each REMAP applicant must provide a statement on the quality processes that will be used to assure that results of the research satisfy the intended project objectives. The QAS should not exceed two consecutively numbered, 8.5x11-inch pages of single-spaced standard 12-point type with 1-inch margins.

2.2 COMPONENTS OF THE QUALITY ASSURANCE STATEMENT

The QAS should, for each item listed below, either present the required information, reference the relevant portion of the project description containing the information, or provide a justification as to why the item does not apply to the proposed research.

1. Discuss the activities to be performed or hypothesis to be tested (reference may be made to the specific page and paragraph number in the application where this information may be found) and criteria for determining acceptable data quality. (Note: Such criteria may be expressed in terms of precision, accuracy, representativeness, completeness, and comparability, or in terms of data quality objectives. Furthermore, these criteria must also be applied to determine the acceptability of existing or secondary data to be used in the project.)

2. Describe the study design, including sample type and location requirements, any statistical analyses that were used to estimate the types and numbers of physical samples required, or equivalent information for studies using survey and interview techniques.

3. Describe the procedures for the handling and custody of samples, including sample collection, identification, preservation, transportation, and storage.

4. Describe the procedures that will be used in the calibration and performance evaluation of the sampling and analytical methods and equipment to be used during the project.

5. Discuss the procedures for data reduction and reporting, including a description of statistical analyses to be used and of any computer models to be designed or utilized with any associated verification and validation techniques.

6. Describe any quantitative and/or qualitative procedures that will be used to evaluate the success of the project, including any plans for peer or other reviews of the study design or analytical methods prior to data collection.

If the applicant believes that the QAS is inappropriate or not applicable to the project, a brief statement of justification should be substituted for the QAS.

3 QUALITY MANAGEMENT PROJECT PLAN (QMPP)

3.1 WHAT IS A QUALITY MANAGEMENT PROJECT PLAN?

If the scope of the project involves significant and complex environmental data operations or environmental technology development, applicants for REMAP research grants may be required to submit a more detailed documentation of the quality assurance and quality control practices to be used in the project. A quality management project plan (QMPP) is a document that includes elements of the QA Statement but it generally contains more information and details about the QA and QC activities planned.

The QMPP's purpose is to provide information to the U.S. Environmental Protection Agency Project Officer (PO) or award official on an applicant's capabilities to provide adequate quality assurance (QA) and quality control (QC) for the proposed work. The QMPP also may be applied to small data collection tasks, small assistance agreements for basic or exploratory research, and similar work of limited scope and duration. The QMPP should demonstrate to the award official that QC procedures are in place to ensure that each project objective is achieved.

The QMPP should be prepared in accordance with the guidance provided in this section and should describe the QC and QA practices to be implemented by the applicant for the proposed project in sufficient detail to present a clear picture of what is to be done and when. The QMPP must be submitted for review and approval by the EPA Project Officer and EPA QA Manager before undertaking any work involving environmental measurements or data generation. Key areas to be addressed include:

- the hypothesis being tested and the objectives of the test(s),
- the measurements (when applicable) that will be taken to achieve those objectives,
- the quality of information (including environmental data) that will be required and how the necessary quality will be obtained, and
- the measurement performance criteria.

Below are several questions to consider and answer as part of planning the QMPP:

- What decision will be made as a result of this research? (Basis for the hypothesis)
- What quantity and quality of data are needed to be able to make the decision (test the hypothesis)?
- What environmental matrix will be tested?
- What type of measurements are planned?
- What is the planned schedule for collecting samples?
- What is the schedule for the laboratory analysis of the samples?
- Will this be a one time sampling event or an ongoing monitoring activity?

3.2 COMPONENTS OF THE QUALITY MANAGEMENT PROJECT PLAN

The following sections should be included in the QMPP:

- Project description;
- Proposed schedule with start and end dates and milestones for the project;
- Statement of the project objectives;
- Description of the experimental design;
- Description of the sampling and analytical methods;
- Description of the process for sample handling and custody;
- List of key project staff;
- Description of how quality will be ensured during the project; and
- Identification of any needed special reports on the QA and QC activities performed, as appropriate.

If any of these items have been covered in detail in the text of the proposal, they may be included in the QMPP by reference to the specific page number in the original application. The content needed for of each of these nine items are described below. Brief examples of text and tables also are given. If a component does not seem to apply, state this and indicate why in a brief discussion in the text. If the information may be elsewhere in the proposal, point to the location in your project narrative.

(1) Project Description

A brief synopsis of the project (e.g., a few concise paragraphs) should describe the purpose of the study, including the hypothesis to be tested and the unique research aspects of the project. Also note other anticipated uses of information or data generated in the project. Particularly important is a description of how the data collection activities will be performed, including the process or environmental system that will be tested. If the project is part of a larger EPA program, describe how it fits in. The abstract included in your proposal may be adequate for this section.

(2) Statement of the Project Objectives

Project objectives should be summarized in this section. Clearly identify the primary goals of the project in quantitative terms, if possible, and state how the anticipated results will achieve the research objectives of the project. For example, a project objective may be stated as:

> *The objective of this project is to demonstrate a removal efficiency of 90 percent or higher at a confidence level of 95 percent for the heavy metals identified in the top 5 centimeters of estuarine sediment.*

Some objectives may not be stated entirely in quantitative terms. The criteria for successful completion of the work should be described; that is, how will one know the objectives of the project have been met?

(3) Description of the Experimental Design

Describe the experimental design of the project with emphasis on the critical and noncritical measurement aspects of the project. Critical measurements are those necessary to achieve the project objectives; noncritical measurements are those used for process control or general background measurements. What must be accomplished for the objectives to be met? Include the sample type and location requirements and any statistical analyses that were used to estimate the types and numbers of samples required. The experimental design should be linked (as much as possible) to the quantitative project objectives discussed in the previous section.

(4) Description of the Sampling and Analytical Methods

The sampling and analytical methods that will be used should be described. When standard methods, such as those published by EPA, ASTM, or the American Public Health Association, are used, a reference to the method with any deviations or choices specifically noted is sufficient documentation. How and how frequently will instruments be calibrated? What standards will be used for calibration and do they have traceability to higher accuracy standards? What are the relevant performance criteria? Consider analytical blanks, instrument response check samples, interferences, and effects of temperature or pressure on the analytical method.

(5) Description of the Process for Sample Handling and Custody

The system should be described for identifying (or numbering) samples, sample containers, required sample volume or mass, avoidance of contamination, preservation, transportation (if applicable), holding times, storage times and conditions (if applicable), and safe final disposal of samples. Samples may be attached as documentation for sample labels. Describe the procedure for recording sample history, sampling conditions, and any other pertinent information. Formal sample custody is usually not necessary but samples must still be tracked in some manner, especially those that are toxic or radioactive. Not all environmental samples are physical samples that can be tracked. For instance, real-time air samples from continuous emission or ambient air monitors will not require sample labels, preservation, or transportation. It is important to note, however, how a gaseous sample will be brought from the point of sampling to the monitor. It also is important that a system be in place to accurately match data to the time and place of the air sampling.

(6) Proposed Schedule with Start and End Dates and Milestones for the Project

The actual start and expected end dates of the project, including intermediate milestones and results, should be identified. A milestone chart or table indicating start or end dates for major milestones may be helpful.

(7) List of the Key Project Staff

All key personnel and their assigned responsibilities should be listed in this section. The list should include geographic locations, telephone and fax numbers, and electronic mail addresses. For managerially complex projects, an organizational chart may be helpful. Any subcontractors or consultants (if used) and their responsibilities should be included. In addition, any special skills or need for training should be determined and steps to provide those skills or training identified. Project personnel and organization may be shown in tabular form, if desired. See example below.

(8) Description of How Quality Will be Ensured During the Project

The process by which quality will be ensured during the project should be described. Some of the key questions that may be asked in developing an appropriate description are:

- Can quantitative objectives be established for quality? Will only qualitative objectives be possible?
- How will the data comparability and representativeness be determined?
- What types of QC samples will be included in the sampling and analysis routines?
- What calculations will be performed and how will the correctness of calculations be ensured?
- What statistical procedures will be used to analyze the data?
- Can the quality of the information or data be independently verified?
- How will success be measured and related to the project's objectives?

The performance criteria for the project should be described here. In addition, any performance evaluations, audits, surveillance, and other assessment procedures planned, should be described, including the procedures to be used for data validation and verification. Also, there should be a discussion of how any corrective actions will be implemented and documented and their effectiveness confirmed for any audits performed.

There should also be a discussion of any plans for peer or other reviews of the design or analytical methods prior to data collection.

(9) Identification of Any Required Reports on the QA and QC Activities Performed

Often, summaries of QA and QC results are included as an appendix to the final report instead of as a separate report, while QA and QC text descriptions may be incorporated into annual reports. Be sure to note your laboratory's QA and QC plans as well as any calibration and verification services to be performed outside your research unit (for example, verification of a microbalance, calibration of a flow meter, or tuning of a spectrophotometer).

4 QUALITY ASSURANCE REQUIREMENTS FOLLOWING ACCEPTANCE

4.1 POSSIBLE QUALITY ASSURANCE PROJECT PLAN REQUIREMENT

After your REMAP proposal has been accepted for funding, there may be questions about the adequacy and suitability of the QA statement or QMPP. It also is possible that the grant's Project Officer and/or other funds administrator may suggest (or insist) that a still more comprehensive QA Project Plan be prepared before beginning any data collection work. If necessary, a term and condition statement will be added to the award document notifying the recipient that work involving environmental data generation may not begin until the EPA Project Officer gives notification that quality assurance plans are adequate. Funds may need to be reserved to create a QA Project Plan(QAPP), if necessary.

Often, a dialogue between the Principal Investigator (PI) and the Project Officer can resolve quality assurance requirements questions. For instance, sections of the QMPP could be expanded or a standard operating procedure for performing a certain task could be prepared and attached to the QMPP as an appendix to supply additional information.

The MED Quality Assurance Officer makes the final decision about whether to require a QA Project Plan(QAPP). Generally, the QAPP typically may be required for studies producing large volumes of data, for studies determined to be controversial by EPA, or for studies of a highly complex nature that may need more extensive documentation of the planning process.

4.2 IMPLEMENTATION

Following approval of the QAS or QMPP, and QAPP, if required, it is EPA's expectation that the elements of the applicable document be implemented as part of the agreement.

REFERENCES

ASQ (American Society for Quality). 1994. *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.* ANSI/ASQC E4-1994. Milwaukee, WI.

U.S. EPA (Environmental Protection Agency). 2000. *Guidance for the Data Quality Objectives Process* EPA/600/R-96/055

U.S. EPA (Environmental Protection Agency). 2000. EPA Order 5360.1, A2, May 2000. *Policy and Program Requirements for the Mandatory EPA Quality System*.

U.S. EPA (Environmental Protection Agency). 1998b. *EPA Guidance on Quality Assurance Project Plans* EPA/600/R-98/018.

U.S. EPA (Environmental Protection Agency). 1999. *EPA Requirements for Quality Assurance Project Plans* (QA/R-5 Interim Final)